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App-Based Treatment in Primary Care for Urinary Incontinence: A Pragmatic, Randomized Controlled Trial

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ABSTRACT

PURPOSE Electronic application (app)-based treatment is promising for common diseases with good conservative management options, such as urinary incontinence (UI) in women, but its effectiveness compared with usual care is unclear. This study set out to determine if app-based treatment for women with stress, urgency, or mixed UI was noninferior to usual care in the primary care setting.

METHODS The URinControl trial is a pragmatic, noninferiority randomized controlled trial in Dutch primary care including adult women with 2 episodes of UI per week. From July 2015 to July 2018, we screened 350 women for eligibility. A stand-alone app-based treatment with pelvic floor muscle and bladder training (URinControl) was compared with usual care according to the Dutch general practitioner guideline for UI treatment. Outcomes measured were change in symptom severity score from baseline to 4 months (primary outcome), impact on disease-specific quality of life, patient-perceived improvement, and number of UI episodes. Noninferiority (<1.5 points) was assessed with linear regression analysis.

RESULTS A total of 262 eligible women were randomized equally; 195 of them had follow-up through 4 months. The change in symptom severity with app-based treatment (−2.16 points; 95% CI, −2.67 to −1.65) was noninferior to that with usual care (−2.56 points; 95% CI, −3.28 to −1.84), with a mean difference of 0.058 points (95% CI, −0.776 to 0.891) between groups. Neither treatment was superior to the other, and both groups showed improvements in outcome measures after treatment.

CONCLUSIONS App-based treatment for women with UI was at least as effective as usual care in the primary care setting. As such, app-based treatments, with their potential advantages of privacy, accessibility, and lower cost, may provide women with a good alternative to consultation.

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INTRODUCTION

Conservative treatment for female urinary incontinence (UI) can be time-consuming, and adherence varies, which limit its effectiveness.¹ Electronic application (app)-based treatment that delivers advice, training, and motivation for managing UI by oneself could offer advantages over usual care, removing the barriers to treatment access and improving adherence to training. We cannot justify prescribing an app for UI, however, unless it has been shown to be at least noninferior to current best practice.

More than 100 apps for UI management are already available, yet evidence for their effectiveness is scarce. Moreover, these apps tend to focus on stress UI alone and to have diverse contents.² In a Swedish study, app treatment improved UI symptoms and quality of life after 3 months compared with postponed treatment and was cost-effective at 12 months.³ A recent small Brazilian study also showed increased adherence to pelvic floor muscle exercises and an improvement in UI symptoms after 3 months

of app-based treatment compared with written instructions alone.⁴ To date, there have been no studies comparing app-based treatment with usual care or treatment for urgency or mixed UI. This gap in the evidence is important because the majority of women with UI have stress, urgency, or mixed-type UI.⁵

We developed an app for use by women with stress, urgency, and mixed UI, requiring no caregiver support. In this study, we specifically assessed whether app-based treatment with this tool was noninferior to usual care provided by general practitioners after 4 months.

METHODS

We conducted a pragmatic, parallel-arm, noninferiority trial of patients with stress, urgency, or mixed UI, the URinControl trial. The complete study protocol was published previously.⁶ After trial commencement, an amendment to the protocol added a process evaluation method and changes to recruit participants from the general population because of a low accrual rate.⁷ We followed the Consolidated Standards of Reporting Trials (CONSORT) guideline and the relevant extensions.^{8,9} The Medical Ethical Review board of the University Medical Center Groningen, the Netherlands, approved this study (METc-number: 2014/574). All participants gave written informed consent.

We recruited participants via primary care, the lay press, and social media in the North of the Netherlands from July 2015 through July 2018. In primary care, women who consulted a primary care clinician for UI were invited during the visit. Women who had previously consulted for UI received postal invitations. Participants recruited through the lay press and social media could sign up directly via a dedicated website to receive information on the study. We confirmed the diagnosis of UI with the Three Incontinence Questions (3IQ) questionnaire.¹⁰

Adult women who experienced at least 2 episodes of UI per week, had access to a smartphone or tablet, and wished to be treated were eligible. We excluded woman with conditions or therapy that could complicate UI, those who had undergone treatment for UI (including surgery) in the previous year, those unable to complete the questionnaire in Dutch, and those with terminal illness or current severe mental illness (eg, dementia). The Supplemental Appendix, available at <https://www.AnnFamMed.org/content/19/2/102/suppl/DC1/>, presents the full inclusion and exclusion criteria.

Interventions

App-Based Treatment

Our app, URinControl, contained a step-by-step program for the self-management of UI that was based on

relevant Dutch general practitioner and international guidance for treating UI.^{11,12} We reported details on the development and content of this app previously.⁶

Participants received a personal account and instructions to download and install the app on their smartphone or tablet. The research team provided technical support only. Each participant was free to contact her general practitioner with any questions regarding UI and to receive additional treatment. The only harm of this treatment that we anticipated was the possibility of performing the exercises in an incorrect manner resulting in a symptom increase; therefore, the app recommends patients visit a doctor if the treatment does not lead to improvement after 3 months, or if the patient develops other health issues.

Usual Care

Participants in the usual care group were referred to their own general practitioner to discuss treatment options. General practitioners were advised to follow the relevant Dutch general practitioner guideline,¹¹ without limitations on the type and mode of treatment. Usual care could consist of any of the following, alone or in combination: instructions on pelvic floor muscle training and/or bladder training; prescription of a pessary, drugs, or absorbent products; and referral to a continence nurse, a pelvic physical therapist, or secondary care.¹¹ General practitioners received no explanation about the content of the app, and the participants received no additional information on UI from the researchers. No harms of usual care were anticipated in the study protocol.

Outcomes

Participants completed the study questionnaires and a 3-day frequency volume chart of voiding before their baseline assessment. At the appointment, they provided information on parity, related medical history, comorbidities, and medications. A trained research physician measured height and weight, and performed a urogynecologic assessment. The physician graded prolapse stage according to the Pelvic Organ Prolapse Quantification System and rated pelvic floor muscle function according to International Continence Society guidance.¹³ Participants completed the web-based questionnaires and frequency volume chart again after 4 months. Our published protocol describes the assessment of outcome measures in further detail.⁶

The primary outcome was the difference between groups in the change of UI severity from baseline to 4 months, assessed by the International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF).^{14,15} Secondary outcomes were the differences between groups in the

change in the condition-specific lower urinary tract symptoms quality of life (ICIQ-LUTS-QoL) and the change in the number of UI episodes per day from baseline to 4 months (assessed with the frequency volume chart) and the patient global impression of improvement of incontinence (PGI-I) at 4 months.¹⁶

Randomization and Blinding

Researchers confirmed eligibility, obtained signed informed consent, collected baseline data, and enrolled participants in the study. Participants were then randomized by 1:1 allocation with random block sizes stratified at the general practitioner level. This process was performed using ALEA (AMV Soluciones),¹⁷ a computer program, to ensure full concealment of group allocation. It was not possible to blind participants, clinicians, or data collection to treatment allocation. The data analysts were blinded at the time of data cleaning and analyses.

Sample Size

The trial has a noninferiority design, which uses a noninferiority margin to reject or accept noninferiority. The margin for noninferiority was set to a 1.5-point difference in the change score for UI severity between groups, based on the requirement for a minimally important difference in the ICIQ-UI-SF of 1.58 points.¹⁸ Sample size calculation was based on an estimated correlation coefficient of 0.4 between baseline and follow-up scores of the ICIQ-UI-SF, power of 0.80, a one-sided type I error of 0.025, and an estimated noninferiority margin of 1.5 points and a standard deviation of 4.1. We needed a sample of 100 participants per group. Allowing for an expected loss to follow-up of up to 20%, we aimed to enroll 250 participants. Although we enrolled women with all types of UI, the study was underpowered to show difference in outcome according to UI type.

Statistical Methods

The primary outcome was analyzed using linear regression analysis. We accepted noninferiority of the app-based treatment group to the usual care group if the upper limit of the 95% confidence interval of the difference in change was less than the noninferiority margin of 1.5 points. If the upper limit of that interval was also less than zero, we concluded that there was statistically significance evidence of the superiority of app-based treatment (2-sided $P < .05$). We performed both intention-to-treat and per-protocol analyses to give conservative outcomes suitable for a noninferiority design.^{19,20} Per-protocol analyses will be presented in full in the appendices. We assessed superiority on an intention-to-treat basis for the secondary outcomes,

using linear regression analysis for the ICIQ-LUTS-QoL and the Mann–Whitney U test for the PGI-I and number of UI episodes. Results were considered statistically significant at $P < .05$.

The regression analyses included baseline UI severity score as a covariate. We also performed analyses in the following prespecified subgroups: incontinence type (stress, urgency, or mixed UI), previous physical therapy for UI (yes vs no), and recruitment strategy (through general practitioner vs media). We used IBM SPSS for Windows, version 24.0 (IBM Corp), for all analyses.

RESULTS

Participants entered the study through 88 general practitioners from 31 practices (201 participants) or through social and other media (149 participants). Of the 350 screened participants, 262 were eligible and randomized evenly (Figure 1). We extended the study to include more participants because loss to follow-up was 6% higher than expected. Follow-up ended on December 20, 2018.

The mean age of the participants was 53 years (range, 20–86 years) and the median duration of UI was 7 years (interquartile range, 4–14 years) (Table 1). Fifty percent (130 participants) reported having mixed UI, and the overall severity of UI was rated as slight by 10% (26 participants), moderate by 64% (166 participants), and severe by 26% (67 participants). Despite randomization, women in the usual care group tended to have more severe UI and a higher frequency of stress UI.

At 4 months, 102 women (78%) in the app-based treatment group and 93 women (71%) in the usual care group were available for the intention-to-treat analysis. Loss to follow-up was associated with young age, higher body mass index, and no prior treatment (data shown in Supplemental Table 1, available at <https://www.AnnFamMed.org/content/19/2/102/suppl/DC1/>). In the app-based treatment group, 96 women (94%) used the app at least once, 6 (6%) underwent pelvic floor muscle training, and 4 (4%) received additional medication. In the usual care group, 75 (81%) visited their general practitioner, of whom 38 (41%) were referred to a therapist or specialist nurse for pelvic floor muscle training and 5 (5%) received medication. No participants were referred to a specialist. Thus, 96 women in the app-based treatment group and 75 women in the usual care group were eligible for the per-protocol analysis. Baseline characteristics of the per-protocol study sample are shown in Supplemental Table 2, available at <https://www.AnnFamMed.org/content/19/2/102/suppl/DC1/>.

In the intention-to-treat analysis, the mean difference in change scores for UI severity (ICIQ-UI SF scores) between the app-based treatment and usual care groups was 0.058 points (95% CI, -0.776 to 0.891) (Table 2). The upper limit of the 95% CI did not reach the noninferiority margin, but it did cross the null hypothesis line of zero (Figure 2). Thus, app-based treatment was noninferior but also nonsuperior to usual care. Both groups showed improvements after

treatment, with mean changes in UI severity of -2.16 points (95% CI, -2.67 to -1.65) in the app-based treatment group and -2.56 points (95% CI, -3.28 to -1.84) in the usual care group. The analysis of the unadjusted scores for change from baseline and the analysis in the per-protocol study sample produced comparable results as shown in Supplemental Table 3 and Supplemental Table 4, available at <https://www.AnnFamMed.org/content/19/2/102/suppl/DC1/>. There was no

evidence in subgroup analyses that the intervention effect differed by UI type, prior physical therapy for UI, or recruitment strategy (Table 3).

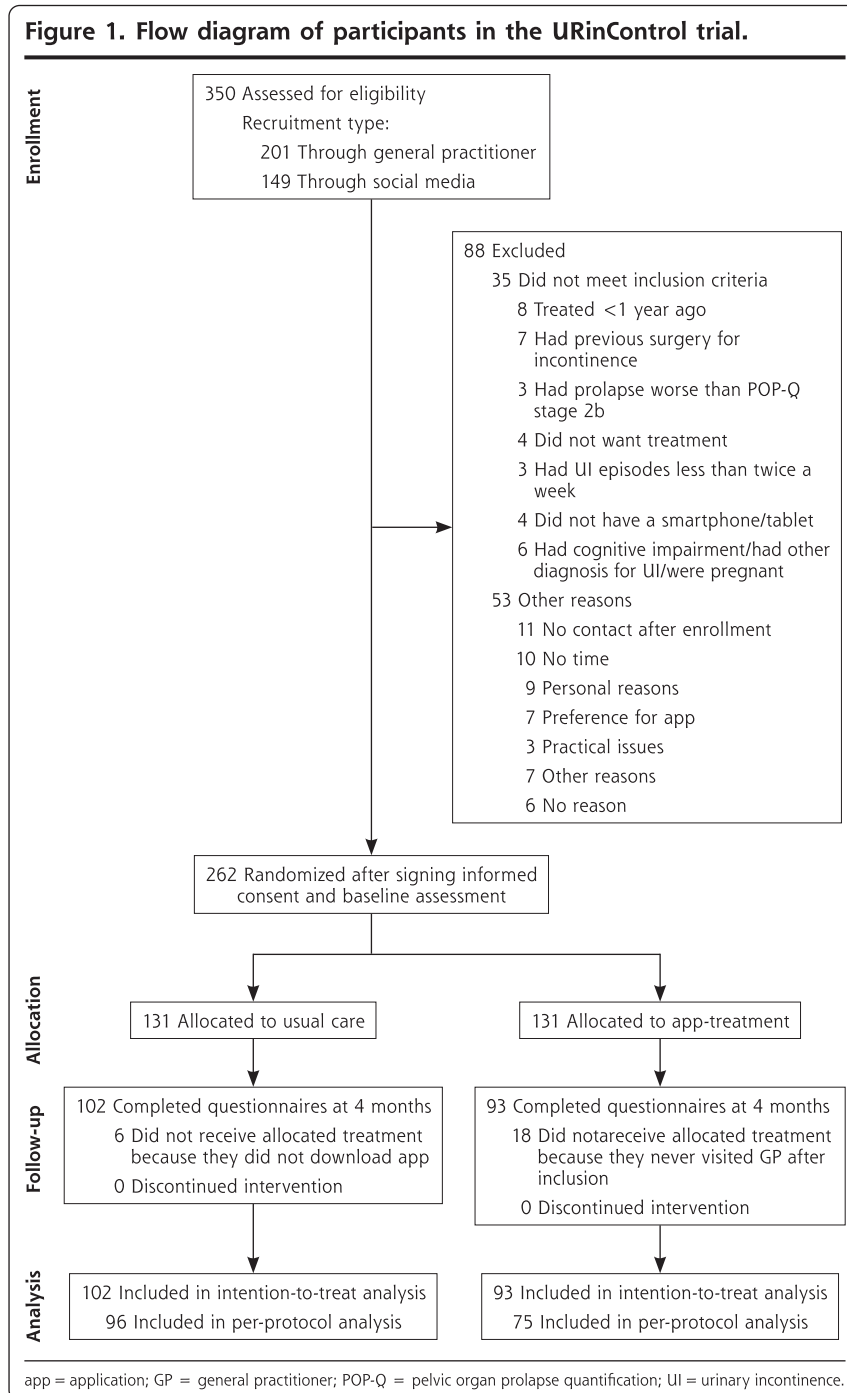
Neither treatment option was superior to the other. In both groups, the disease-specific quality of life (ICIQ-LUTS-QoL score) improved and the number of UI episodes women experienced per day decreased. Also, the majority of women in both the app-based treatment group (65.7%) and the usual care group (66.6%) had improvement based on PGI-I results (Table 2).

DISCUSSION

Among women with stress, urgency, and mixed UI, therapy using the stand-alone URinControl app was at least as effective after 4 months as guideline-based care provided by general practitioners. Both treatments resulted in a clinically relevant decrease of UI severity, improved quality of life, and fewer leakage episodes per day.

The main strength of this study is comparing app-based treatment with recommended usual care.^{5,11} Other strengths lie in the method of app development and the use of a representative study population, comprising women most likely to benefit from app-based treatment. The proportion of women with mixed type UI was higher than expected, which might

Figure 1. Flow diagram of participants in the URinControl trial.



reflect selection bias. Also, patients lost to follow-up were mostly younger without previous treatment, which might reflect a group with lower adherence to treatment. The inclusion criterion requiring availability of a mobile phone or tablet and the recruitment strategy of using social media could have led to a selection of woman with already higher accessibility to health care and especially electronic health (eHealth) tools.

We adopted a pragmatic design because our interest lay in the effectiveness rather than the efficacy of the URinControl app in routine practice. We did not apply any strict treatment protocol in either group. In the usual care group, this approach may have introduced a delay in visiting the general practitioner or a decision not to have pelvic physiotherapy. These issues could have reduced the effectiveness of each treatment approach. We could not blind the participants or clinicians, which may have increased the motivation of participants to follow the new treatment or could have led to disappointment if they received usual care. By contrast, not blinding the general practitioner may have led to stricter guideline adherence.

Recruitment was an important challenge in this study, with a notably lower prevalence of UI in the participating practices than expected based on the known occurrence in Dutch primary care.^{1,11} We therefore changed our recruitment strategy during the study, seeking additional participants through social media.⁷ Subgroup analyses indicated that recruitment did not introduce significant or clinically relevant differences in outcomes, but we cannot be certain that the data reflect all women who seek help for UI from their general practitioners. We attained 195 participants out of the goal of 200 participants with complete follow-up. Our study therefore may be underpowered, especially for the subgroup analyses.

Two trials previously evaluated the effects of app-based treatment on stress UI. Asklund et al³ demonstrated a greater improvement in symptom severity and condition-specific quality of life after app treatment for 3 months in 62 women compared with postponed treatment in 61 women. Their app included information on stress UI, a program for pelvic floor muscle training, and the number and level of exercises performed, as well as a reminder system. Araujo et al⁴ also studied the superiority of adherence to pelvic floor muscle training after 3 months based on app guidance in 17 women compared with that based on written instructions in 16 women, but showed no significant differences

between the groups in either symptom severity or quality of life. Their app included pelvic floor muscle training with electromyography images, reminders, and an overview of their training and UI history.

In our study we combined pelvic floor muscle training for stress UI with bladder training for urgency and mixed UI, where others have focused on stress UI alone.^{3,4} Their choice was possibly motivated by experience with an Internet-based program for stress UI or by the lack of literature on non-face-to-face treatment for urgency and mixed UI.²¹ Such an approach, however, excludes the majority of women with symptomatic UI.

Symptom score reductions were slightly smaller in our study than in previously published studies.^{3,4} This difference could be due to the lower baseline UI severity scores, the inclusion of other types of UI, and the range of options available for usual care in our study. Also, where our participants relied on self-motivation or the reminder function within the app, participants

Table 1. Baseline Characteristics of Study Participants (N = 262)

Characteristic	App-Treatment (n = 131) ^a	Usual Care (n = 131) ^a
Age, mean (SD), y	53.2 (12.8)	51.3 (10.3)
Body mass index, mean (SD), kg/m ²	27.6 (5.5)	28.0 (5.2)
Higher educational level, No. (%) ^b	53 (52.0)	48 (51.6)
≥1 Vaginal births, No. (%)	111 (85.4)	105 (80.2)
Postmenopausal, No. (%)	64 (49.2)	59 (45.0)
Recruitment type, No. (%)		
General practitioner	76 (58.0)	76 (58.0)
Lay press or social media	55 (42.0)	55 (42.0)
Duration of UI, median (IQR), y	7 (4-14)	8 (4-13)
Type of UI, No. (%)		
Stress	50 (38.2)	60 (45.8)
Mixed, stress predominant	37 (28.2)	33 (25.2)
Urgency	12 (9.2)	10 (7.6)
Mixed, urgency predominant	32 (24.4)	28 (21.4)
Previous treatment for UI, No. (%)		
None	99 (76.2)	95 (72.5)
Pessary	0 (0)	1 (0.8)
Physical therapist	31 (23.8)	35 (26.7)
Incontinence severity		
ICIQ-UI-SF score, mean (SD) ^c	9.5 (3.2)	10.3 (3.4)
ICIQ-LUTS-QoL score, mean (SD) ^d	33.9 (8.3)	33.4 (7.8)
UI episodes per day, median (IQR)	1.0 (0.33-2.33)	1.0 (0.33-2.33)

app = application; ICIQ-LUTS-QoL = International Consultation on Incontinence Modular Questionnaire lower urinary tract symptoms quality of life; ICIQ-UI-SF = ICIQ Urinary Incontinence Short Form; IQR = interquartile range; UI = urinary incontinence.

^a Number for analysis ranged from 102 to 131 for the app-treatment group and from 93 to 131 for the usual care group. Some data were missing for the baseline assessment (1 patient) and the baseline questionnaires (3 patients).

^b Assessed at follow-up. Higher: third-level education (vs lower: high school or less).

^c Possible range of scores: 0-21. Higher scores correlate with worse incontinence.

^d Possible range of scores: 19-76. Higher scores correlate with a greater impact of incontinence on quality of life.

in the other studies received a reminder e-mail from the researchers after 4 weeks, or a monthly check by a physical therapist.^{3,4} Adherence to treatment is an important topic in the treatment of UI but also in the continuation of eHealth interventions. For this study, we chose a pragmatic approach for both usual care and the app-based treatment, focusing on change of effect

on UI severity without measuring adherence. With eHealth, however, self-registration within an app and automatically logged data (logdata) offer new ways to track adherence to treatment.

The effect sizes on UI severity were larger than a placebo effect, previously reported at 1.7 points,²² and clinically relevant, with minimally important differences of 3.7 and 2.5 points

tending to be reached for the ICIQ-LUTS-QoL and the ICIQ-UI-SF, respectively.¹⁸ There was an outlier for the ICIQ-UI SF in the app-based treatment group, but we considered all values to be clinically relevant because the scores for the treatment effect in the app-based treatment group were noninferior or comparable to those in the usual care group (ie, greater than 2.5) and were higher than for placebo.²²

The noninferiority of app-based treatment will only be truly clinically relevant if we can demonstrate that it produces a better patient experience or that it is less expensive than usual care, or yields significant long-term improvement. A patient might prefer the accessibility and ease of treatment in her own home or may benefit from some of the integrated functions of the app. Society may benefit from an effective treatment with lower costs. Our findings indicate that a general practitioner can offer both usual care and app-based treatment as options to women seeking help for UI, thanks to the comparable symptom improvement seen with each approach. We included treatment advice for all 3 main types of UI in our app, thereby increasing its applicability and relevance; however, women recruited through social media might have experienced barriers to seeking help directly from their general practitioner, including shame, not knowing there are effective treatments, or simply thinking that their symptoms were a normal part of life.¹

Table 2. Change in Outcomes From Baseline to Follow-Up

Outcome	Change From Baseline		Adjusted Difference (95% CI) or P Value
	App-Treatment (n = 102) ^a	Care as Usual (n = 93)	
ICIQ-UI-SF score, mean (SD)	-2.16 (2.56)	-2.56 (3.51)	0.058 (-0.776 to 0.891)
ICIQ-LUTS-QoL score, mean (SD)	-4.34 (5.44)	-3.78 (5.90)	-0.566 (-2.035 to 0.902)
PGI-I, No. (%)			P = .35 ^b
Very much better	2 (2.0)	11 (11.8)	
Much better	25 (24.5)	20 (21.5)	
A little better	40 (39.2)	31 (33.3)	
No change	30 (29.4)	26 (28.0)	
A little worse	3 (2.9)	2 (2.2)	
Much worse	2 (2.0)	3 (3.2)	
Very much worse	
UI episodes per day	-0.61 ± 2.02	-0.48 ± 1.20	P = .71 ^b

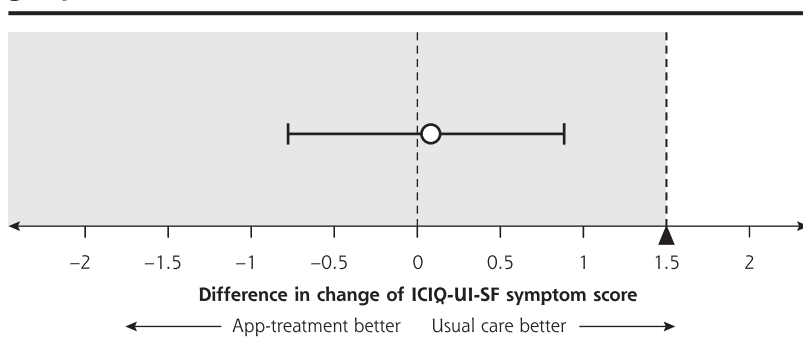
app = application; ICIQ-LUTS-QoL = International Consultation on Incontinence Modular Questionnaire lower urinary tract symptoms quality of life; ICIQ-UI-SF = ICIQ Urinary Incontinence Short Form; PGI-I = patient global impression of improvement; UI = urinary incontinence.

Notes: Number for analysis ranged from 83 to 102 for the app-treatment group and from 74 to 93 for the care as usual group. Analyses performed on an intention-to-treat basis. ICIQ-UI-SF score and ICIQ-LUTS-QoL score are adjusted for baseline. PGI-I and UI (per day) are unadjusted scores.

^a A baseline questionnaire was missing for 1 patient in the app-treatment group for the outcomes of ICIQ-UI-SF score and ICIQ-LUTS-QoL score.

^b Assessed with the U statistic.

Figure 2. Difference in change of ICIQ-UI-SF symptom score between groups.



app = application; ICIQ-UI-SF = International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; UI = urinary incontinence.

Note: Difference in change of ICIQ-UI-SF symptom score: 0.058 (95% CI, -0.776 to 0.891). Change in symptom score with usual care minus change in symptom score with app-treatment. Dashed line at difference in change of 1.5 indicates noninferiority margin. Shaded region to the left of margin indicates values for which app-treatment would be considered noninferior to usual care. Dashed line at 0 represents null hypothesis. Analysis was performed on an intention-to-treat basis and adjusted for baseline scores. (The per-protocol analysis is shown in Supplemental Table 4, available at <https://www.AnnFamMed.org/content/19/2/102/suppl/DC1/>.)

Table 3. Treatment Effect Within Subgroups

Subgroup	No.	Treatment Effect, ICIQ-UI-SF Score (95% CI)
Recruitment type		
General practitioner	107	-0.592 (-1.74 to 0.557)
Lay press or social media	87	0.598 (-0.634 to 1.831)
Type of UI		
Stress	76	-0.154 (-1.337 to 1.029)
Mixed, stress predominant	56	-0.230 (-1.780 to 1.740)
Mixed, urgency predominant	42	-0.345 (-1.972 to 1.281)
Urgency	20	0.401 (-3.910 to 4.710)
Previous physical therapy for UI		
No	137	-1.460 (-1.081 to 0.789)
Yes	57	0.149 (-1.701 to 1.999)

ICIQ-UI-SF = International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; UI = urinary incontinence.

Notes: Linear regression analysis of the treatment effect testing superiority of the difference in change of ICIQ-UI-SF score at 4 months. Analysis was performed on an intention-to-treat basis.

We therefore recommend that general practitioners be more proactive in offering treatment advice and posting information about UI for women in their practice. An app could be an effective way to remedy these unmet needs. In the meantime, we advocate that policy makers support critical websites such as the National Health Service app library so that we may be better placed to translate the available data into guidance for patients and general practitioners.²³

In conclusion, app-based treatment for female stress, urgency, and mixed UI was at least as effective as, but not superior to, usual care. Although eHealth is clearly a promising and evolving route to health care access, researchers and clinicians have a responsibility to ensure that patients receive the best treatments that are currently available. We emphasize the importance of further research and of using appropriate study designs to assess the effects of new apps in a more critical light.²⁴ In doing so, we may find that the purported positive effects of many apps are smaller in clinical settings. Future research should clarify both the long-term outcomes, and barriers to and facilitators of the use and implementation of app-based treatment.

To read or post commentaries in response to this article, go to <https://www.AnnFamMed.org/content/19/2/102/tab-e-letters>.

Key words: app; eHealth; medical informatics; self-management; urinary incontinence; general practice; primary care; women's health; non-inferiority; pragmatic; practice-based research

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Transparency declaration: The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted, any discrepancies from the study as originally planned have been explained.

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Data sharing statement: Data are available on reasonable request. Individual participant data that underlie the results reported in this article, after deidentification, will be available including data dictionaries. Data are available to investigators who provide a methodologically sound proposal for analyses to achieve aims in the approved proposal. The available period begins 9 months after publication and ends 36 months after article publication and after approval of a proposal. Additional information available is the study protocol. There are no additional restrictions on the use of the data. The data are available from M.H. Blanker, m.h.blanker@umcg.nl.

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